

AMENDMENTS TO THE CLAIMS

Claim 1 (Currently Amended): A pharmaceutical gel preparation comprising a mixture of:

(a) D-63153 or a pharmaceutically active salt thereof ~~at least one pharmaceutically active ionic peptide compound having a length of from 8 to 12 amino acids~~ in lyophilized form at a concentration of from 5 to 50 mg of peptide per ml of the preparation, and

(b) an aqueous solution of an inorganic or acetic acid salt at a concentration of from 0.01% to about 0.9% (weight/volume), and wherein the preparation is suitable for administration either immediately after the mixing of (a) and (b) or after a standing time of up to about 120 minutes subsequent to the mixing of (a) and (b).

Claim 2 - 9 (Canceled):

Claim 10 (Currently Amended): The pharmaceutical preparation as claimed in claim 1 wherein the pharmaceutical gel preparation further comprises at least one pharmaceutically active ionic peptide compound ~~is selected~~ selected from the group consisting of cetorelix, teverelix, abarelix, ganirelix, azaline B, antide, detirelix, ramorelix, degarelix, ~~D-63153~~ or their pharmaceutically active salt and mixtures thereof.

Claim 11 (Canceled):

Claim 12 (Currently Amended): The pharmaceutical preparation as claimed in claim 1 wherein ~~the inorganic salt or the acetic acid salt~~ D-63153 is a ~~physiologically tolerated~~ pharmaceutically active salt.

Claim 13 (Previously Presented): The pharmaceutical preparation as claimed in claim 1 wherein the aqueous inorganic salt or acetic acid salt is selected from the group consisting of sodium chloride, calcium chloride, magnesium chloride, sodium acetate, calcium acetate, magnesium acetate and mixtures thereof.

Claim 14 (Currently Amended): The pharmaceutical preparation as claimed in claim 1 wherein the mixture of ~~the pharmaceutically active ionic peptide compound and of the aqueous solution of the inorganic salt or of the acetic acid salt~~ is a liquid suspension or a semisolid dispersion.

Claim 15 (Canceled):

Claim 16 (Currently Amended): The pharmaceutical preparation as claimed in claim 1 wherein the concentration of ~~the pharmaceutically active ionic peptide compound~~ D-63153 is in the range from about 10 to about 50 mg per ml of the total amount of the pharmaceutical preparation.

Claim 17 (Currently Amended): The pharmaceutical preparation as claimed in claim 1 wherein the concentration of ~~the pharmaceutically active ionic peptide compound~~ D-63153 is in the range from about 20 to about 30 mg per ml of the total amount of the pharmaceutical preparation.

Claim 18 (Currently Amended): The pharmaceutical preparation as claimed in claim 1 wherein the concentration of ~~the pharmaceutically active ionic peptide compound~~ D-63153 is in the region of about 25 mg per ml of the total amount of the pharmaceutical preparation.

Claim 19 -24 (Canceled):

Claim 25 (Previously Presented): The pharmaceutical preparation as claimed in claim 1 wherein the concentration of the aqueous inorganic or acetic acid salt solution is in the range from about 0.05% to about 0.5% (weight/volume).

Claim 26 (Previously Presented): The pharmaceutical preparation as claimed in claim 1 wherein the concentration of the aqueous inorganic or acetic acid salt solution is about 0.1% (weight/volume).

Claim 27 (Previously Presented): The pharmaceutical preparation as claimed in claim 1 wherein the inorganic salt is sodium chloride.

Claim 28 (Canceled):

Claim 29 (Previously Presented): The pharmaceutical preparation as claimed in claim 1 wherein the inorganic salt is sodium chloride, and in that the concentration is in the range from 0.05% to about 0.5% (weight/volume).

Claim 30 (Previously Presented): The pharmaceutical preparation as claimed in claim 1 wherein the inorganic salt is sodium chloride, and in that the concentration is about 0.1% (weight/volume).

Claim 31 (Canceled):

Claim 32 (Currently Amended): The pharmaceutical preparation as claimed in claim 1 wherein ~~at least one of the pharmaceutically active ionic peptide compound is D-63153,~~ and the concentration ~~thereof~~ of D-63153 is about 25 mg per ml of the preparation, and ~~in~~ ~~that~~ the inorganic salt is sodium chloride, and the concentration thereof is about 0.1% (weight/volume).

Claim 33 (Currently Amended): A method for producing a pharmaceutical preparation comprising the steps A) bringing together said ~~at least one pharmaceutically active peptide compound~~ D-63153 in lyophilized form and an aqueous solution of an inorganic or acetic acid salt and B) mixing the components.

Claim 34 (Currently Amended): The method for producing a pharmaceutical preparation as claimed in claim 33, wherein the ~~pharmaceutically active ionic peptide compound is D-63153,~~ and the inorganic salt is sodium chloride.

Claim 35 (Currently Amended): The method for producing a pharmaceutical preparation as claimed in claim 33, wherein the ~~pharmaceutically active ionic peptide compound is D-63153,~~ and the concentration ~~thereof~~ of D-63153 is about 25 mg/ml, and ~~in~~ ~~that~~ the inorganic salt is sodium chloride, and the concentration thereof is about 0.1% (weight/volume).

Claim 36 (Previously Presented): The method for producing a pharmaceutical preparation as claimed in claim 33, further comprising the step of sterilization of the peptide formulation by irradiation with gamma rays or electron beams takes place.

Claim 37 (Currently Amended): The method for producing a pharmaceutical preparation as claimed in claim 33, where the production of ~~the peptide formulation (a)~~ takes place with use of aseptic procedures.

Claim 38 (Currently Amended): A kit for producing a pharmaceutical preparation, comprising from 5 to 50 mg per ml of the finished preparation of ~~a pharmaceutically active ionic peptide compound having a length of from 8 to 12 amino acids~~ D-63153 in lyophilized form and an aqueous solution of an inorganic or acetic acid salt at a concentration of from 0.01% to about 0.9% (weight/volume).

Claim 39 (Canceled):

Claim 40 (Currently Amended): The kit as claimed in ~~claim 36~~ claim 38, wherein the D-63153 lyophilizate additionally comprises mannitol.

Claim 41 (Currently Amended): The kit as claimed in ~~claim 36~~ claim 38, wherein the inorganic salt is sodium chloride.

Claim 42 (Currently Amended): The kit as claimed in ~~claim 36~~ claim 38 wherein the concentration of D-63153 is about 25 mg per finished preparation and the concentration of the aqueous sodium chloride solution is about 0.1% weight/volume.

Claim 43 (Currently Amended): A method for treating a patient with a ~~pharmaceutically active peptide compound~~ D-63153, wherein a pharmaceutical preparation as claimed in claim 1 is administered subcutaneously or intramuscularly to the patient.

Claim 44 (Previously Presented): The method as claimed in claim 43 wherein the administered pharmaceutical preparation displays a sustained pharmaceutical activity.

Claim 45 (Previously Presented): The method as claimed in claim 43 wherein the administered pharmaceutical preparation displays a sustained pharmaceutical activity for at least 4 weeks.

Claim 46 (Previously Presented): The method as claimed in claim 43 wherein the administered pharmaceutical preparation displays a sustained pharmaceutical activity for at least 8 weeks.

Claim 47 (Previously Presented): The method as claimed in claim 43 wherein the administered pharmaceutical preparation displays a sustained pharmaceutical activity for at least 12 weeks.

Claim 48 (Currently Amended): A method for treating a hormone-dependent disorder in a patient by subcutaneous or intramuscular administration of a pharmaceutical preparation as claimed in claim 1 in a patient need thereof ~~requiring this~~.

Claim 49 (Currently Amended): A method for treating prostate cancer in a patient by subcutaneous or intramuscular administration of a pharmaceutical preparation as claimed in claim 1 in a patient need thereof ~~requiring this~~.

Claim 50 (Withdrawn; Currently Amended): A method for treating breast cancer in a patient by subcutaneous or intramuscular administration of a pharmaceutical preparation as claimed in claim 1 in a patient need thereof ~~requiring this~~.

Claim 51 (Withdrawn; Currently Amended): A method for treating uterine myomas in a patient by subcutaneous or intramuscular administration of a pharmaceutical preparation as claimed in claim 1 in a patient need thereof ~~requiring this~~.

Claim 52 (Withdrawn; Currently Amended): A method for treating endometriosis in a patient by subcutaneous or intramuscular administration of a pharmaceutical preparation as claimed in claim 1 in a patient need thereof ~~requiring this~~.

Claim 53 (Withdrawn; Currently Amended): A method for treating precocious puberty in a patient by subcutaneous or intramuscular administration of a pharmaceutical preparation as claimed in claim 1 in a patient need thereof ~~requiring this~~.

Claim 54 (Withdrawn; Currently Amended): A method for modifying the reproductive function in a patient by subcutaneous or intramuscular administration of a pharmaceutical preparation as claimed in claim 1 in a patient need thereof ~~requiring this~~.

Claim 55 (Currently Amended): The pharmaceutical preparation as claimed in claim 1 wherein the mixture ~~of the pharmaceutically active ionic peptide compound and of the aqueous solution of the inorganic salt or of the acetic acid salt~~ is a molecular-dispersed or colloidal mixture which may be of liquid to semisolid consistency.

Claim 56 (Previously Presented): The pharmaceutical preparation as claimed in claim 1 wherein a colloidal dispersion is formed by reconstitution.

Claim 57 (Previously Presented): The pharmaceutical preparation as claimed in claim 1 wherein a colloidal dispersion is formed by storage or leaving to stand after reconstitution and changes its viscosity as a function of time and thus improves the reproducibility of the delayed release of active ingredient.

Claim 58 (Currently Amended): A kit comprising a lyophilized ~~pharmaceutically active peptide~~ D-63153 optionally together with one or more pharmaceutically acceptable excipients or additives, and a low-concentration aqueous solution of an inorganic salt.

Claim 59 (Canceled):

Claim 60 (Previously Presented): The kit as claimed in claim 58, wherein the inorganic salt is sodium chloride.